

**Remarks**

This Amendment is responsive to the June 16, 2008 office action. Reexamination and reconsideration of the pending claims is respectfully requested.

**Summary of the Office Action**

**Claims 1-20** were rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al. (US 2003/0216669).

**Claims 1-20** were rejected under 35 U.S.C. 103(a) as being unpatentable over Ateshian et al. (US 6,126,690).

**Claim Rejections under 35 U.S.C. § 103**

**I.**

Claims 1-20 of patent application No. 10/089,467 (the “**Present Application**”) were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lang et al. (US 2003/0216669) (“**Lang**”). However, Lang is not a prior art reference citable under §103(a) to reject the claims of the Present Application.

The Present Application is the U.S. national stage entry of PCT/US00/22053 which claims priority from U.S. provisional applications Nos. 60/148,275, 60/148,277, and 60/148,393, all with the same effective filing date of August 11, 1999. Thus, the Present Application has a priority date of August 11, 1999.

Lang is a continuation-in-part of U.S. patent application No. 10/160,667, filed May 28, 2002, which in turn claims the benefit of U.S. provisional applications Nos. 60/380,695 and 60/380,692 filed May 14, 2002, U.S. provisional application No. 60/363,527 filed March 12, 2002, and U.S. provisional application No. 60/293,488 filed May 25, 2001. Thus, Lang’s earliest 35 U.S.C. § 102(e) prior art date is May 25, 2001 which is later than the Present Application’s priority date of August 11, 1999.

Therefore, Lang is not a prior art reference citable under §103(a) to reject claims of the Present Application. The rejections of claims 1-20 of the Present Application under 35 U.S.C. §103(a) as being unpatentable over Lang are improper and should be removed.

**II.**

Claims 1-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Ateshian et al. (US 6,126,690). However, the office action fails to support a *prima facie* case of obviousness under § 103(a).

MPEP 2142 makes clear that “[t]he examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness.”

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, \_\_\_, 82 USPQ2d 1385, 1396 (2007) noted that the analysis

supporting a rejection under 35 U.S.C. 103 should be made **explicit**. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere **conclusory statements**; instead, there must be some **articulated reasoning** with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR*, 550 U.S. at \_\_\_, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval)... With regard to rejections under 35 U.S.C. 103, the examiner must provide evidence which as a whole shows that the legal determination sought to be proved (i.e., the reference teachings establish a *prima facie* case of obviousness) is more probable than not.

MPEP 2142 (emphasis added).

MPEP 706.02(j) states that

[a]fter indicating that the rejection is under 35 U.S.C. 103, the examiner should set forth in the Office action:

- (A) the relevant teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate,
- (B) the difference or differences in the claim over the applied reference(s),
- (C) the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter, and
- (D) an explanation >as to< why >the claimed invention would have been obvious to< one of ordinary skill in the art at the time the invention was made\*\*.

Moreover,

[i]t is important for an examiner to **properly communicate the basis for a rejection so that the issues can be identified early and the applicant can be given fair opportunity to reply**. Furthermore, if an initially rejected application issues as a patent, the rationale behind an earlier rejection may be important in interpreting the scope of the patent claims. Since issued patents are presumed valid ( 35 U.S.C. 282) and constitute a property right ( 35 U.S.C. 261), the written record must be clear as to the basis for the grant. Since patent examiners cannot normally be compelled to testify in legal proceedings regarding their mental processes (see MPEP § 1701.01), **it is important that the written record clearly explain the rationale for decisions made during prosecution of the application**.

MPEP 706.02(j) (emphasis added).

Finally, MPEP 2141 states that

When making an obviousness rejection, **Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied.** In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness... Once the findings of fact are articulated, **Office personnel must provide an explanation to support an obviousness rejection under 35 U.S.C. 103. 35 U.S.C. 132 requires that the applicant be notified of the reasons for the rejection of the claim so that he or she can decide how best to proceed.** Clearly setting forth findings of fact and the rationale(s) to support a rejection in an Office action leads to the prompt resolution of issues pertinent to patentability... **Any obviousness rejection should include, either explicitly or implicitly in view of the prior art applied, an indication of the level of ordinary skill... Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art...The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.** (emphasis added).

Here, the office action rejects claims 1-20 of the Present Application in two conclusory sentences: "Ateshian et al. discloses or renders obvious a system and associated method for selecting an implant appropriately sized for an anatomical fit, making use of a model or template to visualize the region of interest, including healthy and diseased tissues. Additionally disclosed is imaging complementary healthy joint to ascertain a mirror image of the site in its healthy and functional state." (Office Action, page 3).

The office action does not make explicit the analysis supporting the rejection under 35 U.S.C. § 103 and it does not articulate any reasoning with some rational underpinning to support the legal conclusion of obviousness. The office action does not properly communicate the basis for the rejection as it does not include findings of fact concerning the state of the art, the teachings of the reference applied, and the level of ordinary skill in the art. Further, the office action does not explain why the differences between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art.

In sum, the office action does not clearly articulate the reasons why the invention claimed would have been obvious, thus failing to support a prima facie case of obviousness under 35 U.S.C. 103. The Office has not met its burden of establishing a prima facie case of obviousness. Applicant has been left guessing as of the basis for the rejection and without a fair opportunity for reply.

For these reasons, Applicant kindly requests that the rejection be properly supported on the record or removed.

**Conclusion**

For the reasons set forth above, the pending claims are in condition for allowance. An early allowance of all claims is earnestly solicited.

Applicant has submitted the fee for the extension of time and believes that no additional fees are due at this time. If there are any other fees due in relation to submittal of this communication, please charge to deposit account No. 02-2051, docket No. 28728-65.

Respectfully submitted,

December 10, 2008

Date

/Luis A. Carrion/

Luis A. Carrion  
(Reg. No. 61,255)

**BENESCH, FRIEDLANDER,  
COPLAN & ARONOFF, LLP**

2300 BP Tower  
200 Public Square  
Cleveland, OH 44114-2378  
(216) 363-4500 Telephone  
(216) 363-4588 Facsimile